

QALYs gained, utility scores for responders and nonresponders were derived from UK expert estimates and parent-proxy-ratings. Incremental cost-effectiveness ratios (ICERs) were calculated including a range of scenarios for maintenance treatment over an additional 12 months, and were subjected to multiple sensitivity analyses. **RESULTS:** Eight-week remission rates were 4% (MPH b.i.d.), 23% (MPH-IR t.i.d.), and 47% (MPH-OROS). For cost per response achieved, ICERs were €388 for MPH-OROS versus MPH-IR t.i.d. and €206 versus MPH-IR b.i.d.; ICERs for maintenance of response over 14 (2+12) months were €2,773 for MPH-OROS versus MPH-IR t.i.d. and €2,224 versus MPH-IR b.i.d., assuming that nonresponders discontinue drug treatment. Cost-per-QALY-gained for MPH-OROS versus MPH-IR t.i.d. was between €16,500 and €44,000, or €11,200 to €26,200 after adjustment for the Finnish 42% medication refund policy. Across all sensitivity analyses, MPH-OROS showed extended dominance over MPH-IR t.i.d. when compared to a Do Nothing scenario. **CONCLUSIONS:** By current standards, ICERs for MPH-OROS appear to fall well within the limits considered acceptable, especially considering the limited scope of the analysis (patient symptom improvement only, without taking into account long-term sequelae or impact on caregivers).

MH4

#### **HEALTH SERVICE EXPENDITURES FOR CHILDREN AND ADOLESCENTS WITH AND WITHOUT ATTENTION-DEFICIT/HYPERACTIVITY DISORDER (ADHD) IN GERMANY—IMPACT OF COEXISTING CONDITIONS**

Schlender M<sup>1</sup>, Schwarz O<sup>1</sup>, Trott GE<sup>2</sup>, Viapiano M<sup>3</sup>, Bonauer N<sup>3</sup>  
<sup>1</sup>Institute for Innovation & Valuation in Health Care (InnoVal-HC), Eschborn, Germany, <sup>2</sup>University of Würzburg, Aschaffenburg, Germany, <sup>3</sup>Kassenärztliche Vereinigung Baden-Württemberg, Karlsruhe, Germany

**OBJECTIVES:** Coexisting mental health disorders are common in patients with ADHD and may increase utilization of health care services and therefore expenditures. The present study was designed to address the impact of comorbidities on the direct medical costs incurred by statutory health insurance (SHI) for patients with and without ADHD. **METHODS:** For a retrospective matched cohort study, concomitant diagnoses and health care resource utilization data for patients age 7 to 19 years with a diagnosis of ADHD (F90.0 and/or F90.1) and for a randomly selected control group (matched 1:1 by age and gender) were extracted from the Nordbaden claims database (for year 2003), and were combined with SHI prescription data. Complete datasets were available for 2171 children age 7–12 years and 768 adolescents age 13–19 years with a diagnosis of ADHD, plus the same number of control persons. For costing, resource use was valued applying SHI acquisition costs. Patient subgroups were defined by the (additional) presence of the most prevalent comorbidities, i.e., conduct and personality disorders, mood and affective disorders, specific development disorders, and adjustment disorder. **RESULTS:** Average costs per patient with ADHD were €622/€661 (children/adolescents) compared to €245/€250 for controls. ADHD with coexisting conditions caused the following direct medical expenditures: in the additional presence of conduct and personality disorder, €703/€769; mood and affective disorders, €714/€761; specific development disorders, €630/€766; adjustment disorder, €829/€963. Average costs for patients with these disorders but without ADHD were also increased, and will be reported in detail. **CONCLUSIONS:** The present data are limited since they do neither include costs of inpatient treatment nor cost of ergotherapeutic interventions, which will have to be addressed in future studies. They provide nevertheless, for the

first time, insight into the impact of coexisting conditions on the financial burden for the SHI associated with a diagnosis of ADHD.

#### **PODIUM SESSION I: QUALITY OF LIFE/PREFERENCE-BASED MEASURES I: ISSUES WITH INSTRUMENTS**

QL1

##### **AGGREGATION OF DATA FROM MULTIPLE LANGUAGES AND CULTURES: REPORT FROM THE ISPOR TASK FORCE ON TRANSLATION AND LINGUISTIC VALIDATION**

Wild D<sup>1</sup>, Martin M<sup>2</sup>, Hareendran A<sup>3</sup>, von Maltzahn R<sup>1</sup>

<sup>1</sup>Oxford Outcomes Ltd, Oxford, UK, <sup>2</sup>Health Research Associates Inc, Seattle, WA, USA, <sup>3</sup>Pfizer, Ltd, Sandwich, UK

**OBJECTIVE:** The increasing inclusion of Patient Reported Outcome (PRO) measures in large multi-country trials has introduced many new methodological challenges. PROs are often developed in English and translated into the various languages needed to support these global trials. Data is often pooled and there are concerns about the process, but currently no established criteria, to assure the appropriateness of the aggregation of data derived from multiple languages and cultures. **METHODS:** A literature review was conducted in order to investigate what methods have been used to assess measurement equivalence across translated PROs. Discussions were held between members of the task force and comments were sought from the ISPOR membership. **RESULTS:** A diverse range of methods have been employed to assess measurement equivalence across translated PROs. These include: classical test theory, factor analysis, structural equation modelling (SEM), and Differential Item Functioning (DIF). Basic measurement characteristics such as means, standard deviations etc have been evaluated when the samples are large enough, or basic measurement properties (distribution, internal consistency etc) have been verified in a at least a few languages. If measurement equivalence is lacking it is suggested that qualitative research, analysis of existing trial datasets, and/or consultation with in-country health professionals could be carried out to investigate possible reasons for the lack of equivalence. **CONCLUSION:** While data pooling across languages/cultures is common practice, there is no clear recommendation about methods or the level of measurement equivalence required to determine whether pooling is appropriate or not. There is a need for practical steps to be taken in order to investigate and resolve lack of measurement equivalence and a great need for further research in this area.

QL2

##### **TRANSLATION OF THE COLUMBIA SUICIDE SEVERITY RATING SCALE (C-SSRS) FOR USE IN 33 COUNTRIES**

Fernandez N<sup>1</sup>, Grataloup G<sup>1</sup>, Posner K<sup>2</sup>

<sup>1</sup>Mapi Research Institute, Lyon, France, <sup>2</sup>New York State Psychiatric Institute, New York, NY, USA

**OBJECTIVES:** To help clinicians determine the presence of suicidality, the C-SSRS was developed in US English and contains suggested probes to assess suicidal ideation and behaviour, their severity, and lethality of suicidal attempts. Prior to use in an international study to investigate suicidality, the clinician rated C-SSRS had to be translated into 45 languages for 33 countries. A rigorous methodology was required to ensure conceptual equivalence and cultural relevance across languages. **METHODS:** The process was conducted by specialists in each target country, following a standardized methodology: 1) two forward translations by native target language speakers; 2) comparison and reconciliation of the translations; 3) back translation by a native